DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2014

B. Braun Medical Inc.
Tracy Maddock
Senior Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, PA 18109

Re: K142036
Trade/Device Name: Infusomat Space Volumetric Infusion Pump Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: July 25, 2014
Received: July 28, 2014

Dear Ms. Maddock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142036

Device Name
Infusomat® Space Volumetric Infusion Pump Administration Sets

Indications for Use *(Describe)*
The Infusomat® Space Volumetric Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat Space Volumetric Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
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610-266-0500

Contact: Tracy Maddock, RAC
Sr. Regulatory Affairs Specialist
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DATE: July 25, 2014

DEVICE NAME: Infusomat® Space Volumetric Infusion Pump Intravascular Administration Sets

COMMON OR USUAL NAME: Intravascular Administration Sets

DEVICE CLASSIFICATION: Class II per 21 CFR 880.5440
Intravascular Administration Set, product code FPA
Blood Transfusion Set, product code BRZ
Classification Panel: General Hospital

PREDICATE DEVICES: Infusomat® Space Volumetric Infusion Pump System, K062700

DESCRIPTION:

The Infusomat® Space Volumetric Infusion Pump administration sets are sterile, nonpyrogenic, single-use devices for use with the B. Braun Infusomat® Space Volumetric Infusion Pump for pump and gravity administration of fluids.

Each administration set contains a segment of silicone tubing intended to interface with the linear peristaltic mechanism of the pump. There are two connectors at each end of the pump tube segment and a line loading guide to assist the user in loading the pump segment into the pump. Each set also contains a free flow protection clamp. The clamp is specifically designed to interface with a mating receptacle in the pump and is intended to prevent free flow of fluid when the pump door is opened and the set is removed. There are multiple set configurations including

basic sets, burette sets, additive sets, filtered sets, epidural sets, low adsorption sets, add-on sets, and blood sets.

INTENDED USE:

The Infusomat® Space Volumetric Infusion Pump Administration Sets are intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation/ablation, and enteral. The sets are used for the delivery of medications indicated for infusion therapy including but not limited to drugs like anesthetics, sedatives, analgesics, catecholamines, anticoagulants etc., blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump Administration Sets are intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

SUBSTANTIAL EQUIVALENCE:

Technological Characteristics

Predicate Device – Infusomat® Space Volumetric Infusion Pump System (K062700)

The Infusomat® Space Volumetric Infusion Pump Administration Sets have the same indications for use, principles of operation and technological characteristics as the predicate devices, the administration sets included in the Infusomat® Space Volumetric Infusion Pump System (K062700). The subject sets are constructed of similar materials and are manufactured and sterilized utilizing the same processes.

Performance Testing

The proposed Infusomat® Space Volumetric Infusion Pump Administration Sets were subjected to functional and performance testing to demonstrate that the sets perform as intended.

The following testing was performed:

- Visual inspection
- Simulated use
- Durability
- Flow rate
- Occlusion
- Tensile Strength
- Pressure Testing
- Volumetric accuracy with Infusomat® Space Volumetric Infusion Pump

Results of the testing demonstrate that the proposed device performs similarly to the predicate device and can be used safely and effectively according to its intended use. No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

CONCLUSION:

Results of functional and performance testing conducted on the proposed device demonstrate that the administration sets are safe and perform as intended. The differences, between subject device and predicate device, do not raise any new issues of safety and effectiveness. The Infusomat® Space Pump Administration Sets, therefore, are substantially equivalent to the predicate device.